

Appl. No. 10/748,192
Amendment dated: April 9, 2008
Reply to OA of: January 9, 2008

REMARKS

Applicants have amended the claims to more particularly define the invention taking into consideration the outstanding Official Action. Applicants have amended claim 8 to correct an obvious typographical error. Claim 10 has been corrected to remove the use limitation and claims 11-14 added to further aspects of the invention as defined in the application as originally filed. In this regard, see page 7 and the working examples especially figures 2 and 3 for the temperature range of 23-27 degrees. Applicants submit that the claims now present in the application are fully supported by the specification as originally filed and no new matter is introduced.

Applicants note with appreciation that Applicants election with traverse in the reply filed on October 19, 2007 is acknowledged and found persuasive for the reasons set forth on page 2 of the outstanding Official Action. As such, the species election requirement is withdrawn and claims 1-10 are pending in the present application.

Applicants most respectfully submit that all of the claims now present in the application are in full compliance with 35 USC 112 and clearly patentable over the references of record.

The rejection of claims 1-10 under 35 USC 103(a) as being unpatentable over U.S. Patent No. 5,543,158 to Gref et al. and in view of U.S. Patent No. 6,592,899 to Fowers et al. has been carefully considered but is most respectfully traversed in view of the amendments to the claims and the following comments.

The polymer used in US 6,592,899 (Fowers et al.) was biodegradable and served just as the matrix to control the release rate by diffusion during the treatment. In US 5,543,158 (Gref et al.), the biodegradable polymer formed solid particles and directly encapsulated the drugs. It is well known that degradation of the polymer will generate plenty of acids and decrease pH value below 1.0, which could cause active agents decomposed or inactivated.

In the present invention, the thermogelling hydrogel serving as the matrix is biodegradable. The release rate is controlled by diffusion as well as erosion of the

polymer. The release mechanism is totally different and avoids the burst rate problem of the prior art as noted on page 7, at line 5. In addition, Applicants used oil (or water in oil emulsion) instead of degradable polymer to encapsulate the drugs. The design will prevent the drug from possible damages by acids generated from degrading polymer (hydrogel).

With reference to the bridging paragraph on page 4-5 in the specification, the present invention uses the oil phase to embed the therapeutic agents, and this is also defined in claim 1 of the present application. However, Gref teaches the particles as shown in FIG. 1 of US 5,543,158, and those particles consist of biodegradable core with encapsulated drug and PEG chains on the surface thereof. That is, the biodegradable material is used to encapsulate drug in the Gref's teaching. This teaching is obviously different from that of the present invention (i.e. the oil phase, not biodegradable polymer, is used to embed the therapeutic agents).

Furthermore, Fowers teaches the polymeric drug delivery composition comprising drug, biodegradable polyester oligomer, and biodegradable copolymer. With reference to the bridging paragraph of US 6,592,899, the biodegradable polyester is preferably synthesized from monomers selected from the group consisting of lactide, lactic acid, glycolide, glycolic acid, ϵ -caprolactone, ϵ -hydroxy hexanoic acid, δ -butyrolactone, δ -hydroxy butyric acid, δ -valerolactone, δ -hydroxy valeric acid, hydroxybutyric acids, malic acid, or copolymers thereof. Although the Examiner infers that the fatty acid ester of butyric acid can be used as an oil phase carrier, the Fowers actually does not teach that "polyester" of butyric acid can be used as an "oil phase" carrier.


Besides, the delivery system disclosed in the present invention is temperature-sensitive and a thermogelling emulsion, The oil phase carrier and the temperature-sensitive polymer solution in the delivery system are mixed mutually to form an emulsion. This emulsion is a liquid while the temperature thereof is below a lower critical solution temperature (LCST), and transforms into a gel while the temperature thereof is above said lower critical solution temperature. These features

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all are not disclosed in US 5,543,158 and US 6,592,899. Therefore, one skilled in the art cannot accomplish the present invention simply through the combination of the cited references (US 5,543,158 and US 6,592,899), and thus the present invention should be patentable. Accordingly, it is most respectfully requested that this rejection be withdrawn.

In view of the above comments and further amendments to the claims, favorable reconsideration and allowance of all the claims now present in the application are most respectfully requested.

Respectfully submitted,
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